REMARKS

In the present invention, claims 1-7 are pending with claims 1 and 3 as the only independent claims. Claims 2 and 4-7 depend directly or indirectly from one of claims 1 or 3.

The Present Application Is Specifically Directed To A Cardiac Ablation Apparatus

Because the Examiner is relying on a reference that concerns coagulation, cauterization, and cutting of tissue, which are very different objectives that employ substantially different methods and apparatus from the present invention, the following discussion of claims 1 and 3 and the particular benefits of the present invention to cardiac ablation is provided.

First, it must be emphasized that claims 1-7 of the present application are generally directed to an apparatus for forming a narrow ablation line in cardiac tissue. More specifically, independent claim 1 is expressly directed to a device for clamping and ablating cardiac tissue. As recited in claim 1, such device includes, inter alia, first and second jaws which are relatively movable between a first open position and a second clamped position in which the jaws are substantially parallel. At least portions of the jaws are parallel through a range of tissue clamping spacing. Each jaw has opposed clamped surfaces, which each have a width. In accordance with claim 1, first and second elongated electrodes extend along the clamping surface of the respective jaw and form a part of the clamping surface. Each electrode has a tissue contacting portion which has a width. Also, each clamping surface includes non-conductive portions disposed on each side of the tissue contacting portion of each electrode. Further, the width of the clamping surface exclusive of the width of the tissue contacting portion of each electrode is wider than the width of the tissue contacting portion. As further recited in claim 1, the electrodes are in

face-to-face relationship and are adapted to be connected to an RF energy source so that, when activated, the electrodes are of opposite polarity and are operable to create a line of ablation therebetween narrower than the width of the clamping surface.

It should be noted that the ablation called for in the present claims is a medical procedure which is particularly useful in treating abnormal heart rhythms resulting in atrial fibrillation. The claimed apparatus beneficially provides for the formation of controlled ablation line(s) in cardiac tissue, which gives rise to scar tissue that blocks the pathway of an abnormal electrical impulse but otherwise does not substantially impair the function of the heart tissue. Thus, the relatively narrow ablation line created by the claimed apparatus blocks the abnormal electrical impulse from being conducted through the heart, allowing the normal conduction of impulses through the proper pathway to control heart rhythm, without cutting, cauterizing or coagulating the other clamped tissue between the jaws or coagulating tissue disposed outside of the jaws in the manner described in the cited art.

In the present invention, the ablation line is created using a bipolar radiofrequency (RF) energy that is applied to electrodes carried by the jaws of the ablation apparatus. Among the benefits provided by the ablation apparatus of the present application, energy is applied to the tissue between the closed jaws only to the extent to disrupt or break the pathway of the aberrant electrical impulse by forming a relatively narrow line of ablation. This helps to reduce other damage to cardiac tissue such as damage that may result from thermal spread beyond the jaws and/or from visible coagulation in tissue that is disposed around the outside of the jaws and around the tissue clamped between the jaws.

Applicant's disclosure describes and shows that the illustrated apparatus provides a relatively narrower ablation line as compared to the clamping area provided by the jaws. In Figs. 28-51, for example, the electrode/jaw arrangements show that the tissue contacting portion of each electrode is narrower than the associated clamping surface. At paragraph 102 of the published application, applicant's specification discloses that:

> Importantly, Fig. 9 shows that the electrode/clamped configuration provides a clamped zone of tissue that is wider than the tissue zone of ablated tissue. This is achieved by using an electrode that is narrower than the clamped tissue width, and preferably less than one-third of the clamped tissue width.

At paragraph 103 of the published application, applicant's disclosure states that the distance between the electrodes may be minimized "so that the ablation zone remains narrow." (emphasis added). Thus, when the electrodes are connected to an electrical energy source, such electrical energy is conducted between the electrodes along a line or zone of ablation narrower than the clamped zone of tissue.

Applicant's disclosure explains several added benefits of the claimed electrode/jaw arrangement. Among such benefits, in paragraph 103, applicant's disclosure expressly teaches a reduced risk associated with thrombus formation by providing a relatively narrower ablation zone than the clamping zone.

Accordingly, claims 1-7 provide an ablation apparatus having benefits as discussed above for forming relatively narrow, non-conductive lines of ablation in tissue without excessive tissue damage.

The Cited Reference is Significantly Different from the Claimed Ablation Apparatus

The Final Office Action relies upon the apparatus shown and described in Fig. 5 of U.S. Statutory Invention Registration H1745 to Paraschac (Paraschac). However, it is respectfully

submitted that there are fundamental differences in structure and function which make clear that Paraschac is not analogous to the claimed ablation apparatus. Accordingly, reconsideration and allowance of the claimed subject matter is respectfully requested.

It must be emphasized that Paraschac is specifically designed for different and dramatically more traumatic uses than ablation. Specifically, Paraschac discloses a bipolar coagulation device that is used for coagulating, cauterizing and cutting tissue so that coagulating tissue may be cut without undue bleeding. "Coagulation" causes tissue cells to be ruptured and dried. (Stedman's Medical Dictionary 25th Ed.) "Cauterization" causes the deadening or destruction of tissue. Consequently, the instrument in Paraschac has structural requirements and power conditions which are sufficient to coagulate or cauterize tissue to the point at which the tissue may be severed without blood flow.

In contrast to the claimed electrode/jaw arrangement, the structure of Paraschac intentionally teaches a wide treatment zone which essentially cauterizes the entire lateral extent of tissue disposed between the jaws so as to cauterize the tissue prior to cutting and provide a band of cauterized tissue on both sides of the line where the tissue is severed. For example, in the embodiment of Figs. 5 and 6 of Paraschac, each jaw 116, 117 includes a respective U-shaped electrode 147, 148 which is arranged to form two wide surfaces disposed on opposite sides of a knife-receiving channel 143. The electrical current in this arrangement includes diagonal current flow, as between offset electrodes separated by the knife channel 143. Thus, Paraschac's structure cauterizes the tissue on both sides of the knife-receiving channel 143 - and the tissue disposed across the channel 143 -- to avoid bleeding of such tissue after cutting.

Further, Paraschac intentionally creates a treatment zone which is, in fact, wider than (not narrower than) the width of the jaws in contrast to the claimed invention. Paraschac expressly requires that its invention "create a selective region of visible coagulation around the end effector to provide visual feedback to the surgeon" for determining when to stop the electrical current. (Column 7, lines 1-3, emphasis added). Throughout its disclosure, Paraschac clearly and consistently touts the advantages of providing a visible region of coagulation -- i.e., "feedback region" -- in tissue disposed outside of the jaws with each of its disclosed embodiments, including the embodiment shown in Figs. 5 and 6 which was relied upon in the Final Office Action (column 3, line 66 to column 4, line 6; column 4, lines 28-33; column 5, lines 42-48 and Fig. 6; column 6, line 67 to column 7, line 3).

In the embodiment of Figs. 5 and 6 of Paraschac, outer or "feedback" electrodes 170 and 172 are the exposed outside surfaces of respective electrodes 147, 148 on each jaw. Such outer electrodes 170, 172 create the feedback region of visible coagulation in an area of tissue 197 surrounding the jaws of the end effector such as shown in Fig. 6. Accordingly, the treatment zone in Paraschac spans a width which is larger than the clamping surface to cauterize tissue which surrounds the end effector so as to provide a visual indication of tissue cauterization.

In contrast, the claimed cardiac ablation apparatus in this application only performs relative narrow levels of ablation to the extent necessary to stop the conduction of the aberrant electrical impulse. The claimed apparatus does not otherwise coagulate or cut tissue in addition to performing such ablation. The claimed cardiac ablation apparatus specifically aims to reduce trauma to cardiac tissue and employs an associated

structure and energy source that are commensurate with such objectives, as contrasted to the much more traumatic coagulating, cauterizing and cutting procedures disclosed in Paraschac. Further, unlike Paraschac, the claimed apparatus, because it performs such ablation in a relatively narrow treatment zone, would not provide a visible feedback region of coagulated tissue disposed outside of the sides of the jaws which is the result of added damage to cardiac tissue.

It is respectfully submitted that persons of ordinary skill would realize that Paraschac's bipolar coagulation device is fundamentally different and clearly contrary to the requirements and conditions which are necessary for ablation. Paraschac teaches and suggests a substantially more traumatic medical procedure to human tissue than ablation which, if substituted for ablation, would very likely result in irreparable and potentially fatal damage to heart tissue.

Also in contrast to the claimed apparatus, the bipolar coagulation device disclosed in Paraschac does not contemplate treatment of cardiac tissue. The claimed apparatus on the other hand, is expressly directed to cardiac ablation apparatus, where it is desirable to avoid unnecessary trauma to heart tissue and reduce harm to normal heart functioning. The coagulating, cauterizing and cutting in Paraschac does not treat heart tissue and, in fact, is completely silent that it may be used for cardiac tissue treatment or that it reduces risks associated with thrombus formation within the heart. And for good reason -- the structure and operation of Paraschac's device is inconsistent with the objectives of the present invention and uniquely unsuited for forming ablation lines on cardiac tissue. Thus, not only is the disclosed coagulation device of Paraschac simply not contemplated for any use in cardiac ablation, any use of such instrument for cardiac ablation would create significant

damage and destruction of heart tissue, which is counterintuitive to the benefits of the claimed ablation which aims to avoid undue trauma to heart tissue.

Accordingly, there are fundamental differences between such procedure and the claimed ablation apparatus for all of the above reasons. Thus, these differences are respectfully believed to be persuasive to show that Paraschac is fundamentally different and thus is not relevant to the claimed cardiac ablation apparatus.

Paraschac Does Not Teach Or Suggest Additional Claimed Features

It is noted that the Final Office Action only rejects the claimed invention under 35 U.S.C. Section 103 based on Paraschac, and the prior rejection under Section 102(b) based on Paraschac has been withdrawn. Accordingly, the only outstanding rejection to be addressed is the Section 103 rejection.

It is respectfully submitted that it would not have been obvious to modify Paraschac to achieve the claimed invention in view of its clear and consistent teachings to the contrary. The relevant legal authority makes clear that hindsight-basis obviousness, i.e., obviousness which uses the teachings provided by the applicant's disclosure as a guide to modify the cited art, may not be relied upon to render the claims obvious. As applied to the present situation, it is respectfully believed that there is no motivation in Paraschac to make the alleged modification in the absence of the disclosure provided by the present application.

The Final Office Action relies upon one sentence at column 7, lines 3-4 in Paraschac to support that the claimed invention is an obvious modification. However, it is respectfully submitted that this sentence is being read out of context in a manner which is contrary to the teachings of Paraschac. Such sentence must be read and understood with Paraschac's entire

disclosure, which, as exemplified by the immediately preceding statement, is clearly directed to an invention "intended to create a selective region of visible coagulation around the end effector to provide a visual feedback to the surgeon. (column 7, lines 1-3) (emphasis added).

Clearly, the sentence that is being relied upon actually teaches a variation in "size" of the outer or "active electrode" for providing a feedback region of visible coagulation around the outside of the jaw. This teaching is explained in Paraschac's description of the embodiment of Figs 5 and 6, i.e.:

> The size and shape of outer electrodes 170 and 172 may be adjusted by selectively depositing more or less insulation in the transition regions of electrodes 147 and 148 respectively. Control of the size and shape of the feedback region in treated tissue may be achieved, at least in part, by controlling the size and shape of the outer electrodes, for example, by controlling the size and shape of outer electrodes 170 and 172. For the purposes of this application, outer electrodes may also be referred to as feedback or thermal spread electrodes. (column 5, lines 17-27) (emphasis added).

Although Paraschac teaches that the size of the outer electrodes 170, 172 in Figs. 5 and 6 may be varied, these are the electrode surfaces that form the visible feedback region. Paraschac clearly teaches that the outer electrodes 170, 172 must have a size that creates a visible feedback region of coagulated tissue 197 surrounding the end effector, as shown in Fig. 6." (column 5, lines 44-48). In fact, Paraschac consistently teaches the importance of providing such feedback region throughout its disclosure so that the outer electrodes 170, 172 must be present in some form.

Other portions of Paraschac's disclosure are consistent with this teaching, including at column 4, lines 30-37, which describes the embodiment of Fig. 3:

> [A] small portion of the current will flow outside the region between grasping surfaces 27 and 36,

> coagulating tissue outside that region and providing visual confirmation of coagulation. The size and shape of the feedback region may be varied by varying the portion of outer surface 32 and 34 which are not covered by insulative coating i.e. by varying the size and location of outer electrodes 29 and 39. (emphasis added).

Paraschac expressly teaches that the outer electrodes 29 and 39 in Fig. 3 must provide "the surgeon with visible evidence of coagulation" in a feedback or "coagulated region around the outside of end effector 10." (column 4, lines 1-6, emphasis added). Thus, while the outer electrodes 29 and 39 may be varied by the extent of the insulative coating on the outer jaw surface, such outer electrodes must have a sufficient size for providing a visible feedback region disposed outside of the jaws.

This teaching is also consistent with the paragraph in which the sentence that is being relied upon appears. The first sentence of that paragraph specifically refers to "the outside of bipolar electrode jaws" and, as such, is clearly referring to the outer electrode surfaces. (column 6, lines 60-67) (emphasis added). Thus, Paraschac only teaches or suggests variations in size of the outer electrode surfaces 170, 172 to vary the visual feedback region and is otherwise completely silent as to any modification in size for the two wide tissue grasping surfaces of the electrodes 147, 148 disposed on opposed sides of the knife channel 143.

In fact, it would not be obvious to modify the size or shape of the tissue grasping surfaces of the electrodes 147, 148 in Paraschac. In Fig. 5, Paraschac clearly requires that the electrodes 147, 148 must be wide enough to extend on either side of a knife-cutting channel 143 for cauterizing the tissue clamped between the jaws prior to cutting to prevent bleeding. Paraschac is completely silent that the tissue grasping surface

of the electrodes 147, 148 may be reduced in size in any way. Further, any reduction in size of the tissue grasping surfaces of the electrodes 147, 148 is opposed to providing sufficient cauterization prior to cutting that avoids bleeding in the tissue after cutting.

Further, Paraschac teaches away from any modification in size of the tissue grasping surface of the electrodes 147, 148 for another reason. In Fig. 5, the tissue grasping surfaces of Paraschac's electrodes 147, 148 must extend to each outer jaw surface to form the outer or feedback electrode surfaces 170, 172. Thus, Paraschac actually teaches away from a clamping surface exclusive of the width of the tissue contacting portion of the electrode that is wider than the width of the tissue contacting portion, as in the claimed invention.

Accordingly, for all the above reasons, the claims are respectfully believed to be allowable.

Paraschac Does Not Teach Or Suggest Jaws That Are Parallel

In addition, Paraschac is different from the claimed subject matter for another reason. Paraschac does not teach or suggest that at least portions of the jaws are parallel through a range of tissue clamping spacing, as required by the claims.

The Office Action relies upon the end effector 210 disclosed in Fig. 7 as teaching or suggesting parallel jaws. However, it is noted that the embodiment in Fig. 7 shows only an exploded view of a portion of a modified end effector 210 with variations as compared to the pivotable end effectors that are shown in Figs. 4 and 5. It is apparent that Fig. 7 omits other portions of the end effector that are identical to Figs. 4 and 5 -- i.e., that the jaws are pivotable -- for purposes of simplification.

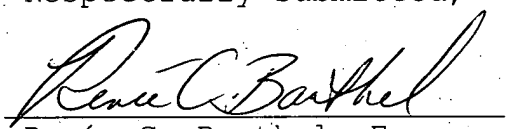
In fact, throughout its disclosure, Paraschac consistently teaches and suggests end effectors having pivotable jaws such as

shown in Figs. 4 and 5. In each of the embodiments of Figs. 4 and 5, a closure tube 420 or 115 is employed to pivotably move the jaws relative to one another. Paraschac clearly does not disclose any other type of closure or otherwise indicate that the closure of the end effector in Fig. 7 is different from the closure tubes 420 and 115 disclosed in Figs. 4 and 5. Thus, the modified end effector in Fig. 7 of Paraschac does not disclose or suggest that at least portions of the jaws are parallel through a range of tissue clamping spacing, in contrast to the claims.

Conclusion

For all the above reasons, it is respectfully requested that the claimed subject matter is not anticipated and would not have been obvious to a person of ordinary skill in view of Paraschac. It is further respectfully requested that the pending claims as amended be reconsidered and allowed.

Respectfully submitted,

Date: February 9, 2006 By: 

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